--REMARKS--

The Applicant has carefully reviewed the statements the Examiner presented in rejecting all of the claims of the application and has also carefully reviewed the cited reference upon which the rejections are based. The Applicant respectfully requests reconsideration and re-examination of the claims of the application in view of the Applicant's responses to the rejection of the claims presented herein. The Applicant respectfully submits that the rejections have been traversed through a declaration, factual presentation based on the cited reference, through arguments overcoming anticipation, and through specification and claim amendments.

Below, the Applicant traverses each of the Examiner's rejections to the claims in the order presented in the Non-final Office Action mailed April 4, 2006.

A declaration by the Applicant is attached to this Amendment.

Claims Rejections under 35USC §112:

The Examiner rejected Claims 1-11, 13-23 and 25-55 as failing to comply with the enablement requirement of 35USC §112. The Examiner states that the claims contain subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant respectfully disagrees and believes that one having ordinary skill in the art would find the applicant's disclosure fully enabling. The Applicant notes that the first Office Action mailed April 29, 2005 from a different Examiner in Art Unit 3714 contained no enablement objections or rejections. A declaration from the Applicant is attached to this Amendment D further supporting the enablement of the Applicant disclosure of the invention.

The Examiner takes the position that the Specification of the application does not teach a methodology or procedure for how the electronic control unit will interface with the rest of the system, cause pressurization or depressurize the pressure vessel, or maintain the intended pressures. The Examiner goes on to state that what element is intended to generate pressurized fluid is not shown or taught in the Specification as originally filed. The Specification was amended to include information originally filed in the claims of the application. The Applicant respectively submits that the electronic control unit is clearly defined in the first paragraph of the DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT where its states "the master controller unit of the apparatus interfacing with the fluid pressure sensor 130, the fluid pressure control element 110, the user operated controls 160, an optional data interface to the electronic sphygmomanometer 170 and the optional data display 180." An arrow is shown in Figure 1 between the electronic control unit 140 and the gas pressure control element 110 to show information exchange. The same paragraph of the Specification clearly states that one embodiment of the electronic control unit 140 is circuitry including a microprocessor. It is very well known in the art of automatic electronic sphygmomanometers that electronic circuitry, with a microprocessor or circuitry performing similar functions, automatically controls functions of pumping air into a blood pressure cuff to halt the blood flow in an arm of a patient and the circuitry also controls the release rate of pressure from the cuff through an electronically controlled valve system as the blood pressure levels are recorded electronically. Those having ordinary skill in art of blood pressure devices such as the ubiquitous, automatic electronic sphygmomanometer are well versed in the operation of electronically controlling the pressure in a pressure vessel by electronically interfacing a pressurized air source to increase pressure in the vessel, a pressure sensor to measure pressure in the vessel, and an electromechanical valve system to reduce pressure in the vessel. This or similar pressure control function has been incorporated into automatic sphygmomanometers for many years and was very well known to those having ordinary skill in the art at the time of filing of the instant application. Therefore, the Applicant submits that one of ordinary skill in the art would find it obvious how the electronic control unit interfaces with the rest of the system, to cause pressurization or to depressurize the pressure vessel, or maintain the intended pressures in the instant invention.

For further support of enablement, refer to the attached declaration. The declaration points to commonality of interfaced components within automatic electronic blood pressure measurement device to pressurize and depressurize of a blood pressure cuff. In contrast to the prior art, one novelty of the instant invention is a feature of providing a tactile interface whereby a user can feel the pressure inside a pressure vessel representative of human diastolic and/or systolic pressures at normal and/or abnormal levels. Another novelty of the instant invention is the maintaining of the various pressure levels in the pressure vessel in a periodic manner to simulate a human cardiac pulse to further provide important tactile feedback to the user touching the vessel. The Specification of the instant invention teaches that the electronic control unit 140 electronically manages that task in one embodiment.

The Applicant also respectively submits that the element to generate pressurized fluid is clearly taught as element 100 in Figure 1 and in the specification in the first paragraph under the DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT where it is stated "The pressurized fluid generator 100 is an electric powered pump in one embodiment, a compressed fluid storage vessel in another embodiment, and a manually operated pump in yet another embodiment." Further the Applicant submits that electric powered pumps, compressed fluid storage vessels, and manually powered pumps were all very well known elements to one having skill in the art of blood pressure related devices and fluid mechanical systems at the time the instant application was filed.

The Examiner also points to a lack of mention by the Applicant of an "electric solenoid controlled valve system" as in claim 8 or how it is incorporated into the instant invention. The Applicant has amended the Specification to include the electric solenoid controlled valve system as it was included in Claim 8 as originally filed in the Application. According to MPEP 608.01(l):

> *In establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it. Where subject matter not shown in the drawing or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and requirement made to amend the drawing and description to show this subject matter. The claim should not be attacked either by objection or rejection because this subject matter is lacking in the drawing and description. It is the drawing and description that are defective, not the claim.*
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> *It is, of course, to be understood that this disclosure in the claim must be sufficiently specific and detailed to support the necessary amendment of the drawing and description.*

The Examiner points to Claim 9 and states that although an electric powered pump is mentioned in the Specification, how it is related to the other components of the invention or controlled to perform the recited features and functions is not taught. The Applicant respectfully disagrees and points to the Specification and drawings for the relevant teaching. From Figure 1 it is shown that the pressurized gas generator 100 (electric powered pump in one embodiment) is pneumatically connected by plumbing to the gas pressure control element 110 which is clearly taught in the Specification to regulate the pressure in the pressure vessel 120 (first paragraph in DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT.) Also, the second sentence of the same paragraph states "A pressurized fluid generator 100 provides a fluid above the ambient pressure to serve as the working medium within the pressure vessel with moveable surface providing tactile interface 120." This statement along with Figure 1 clearly shows how the electric powered pump, the pressure control element, and the pressure vessel with moveable surface are related to each other in the invention. Further, this first paragraph clearly describes how the "A fluid pressure control element 110 serves as a pressure regulator to control the pressure level within the pressure vessel with moveable surface 120. A fluid pressure sensor 130 senses the pressure level within the pressure vessel with moveable surface 120 and provides pressure data feedback to the electronic control unit 140." Finally, the Specification has been modified to include "In one embodiment of the invention, the fluid pressure control element 120 is an electromechanically actuated pressure regulator. In another embodiment of the invention, the fluid pressure control element 120 is an electric solenoid controlled valve system."

Regarding Claim 13, the Examiner states that the Applicant does not show how the hollow bulb components could be modified to produce simulated pressures in a cuff embodiment. The Applicant submits that a cuff embodiment is extremely well known in the art of blood pressure measurement devices. Further, the applicant submits that dependent Claim 13 does not modify a hollow bulb as suggested by the Examiner, but rather further defines the term "pressure vessel" recited in independent Claim 1.

Regarding Claim 17, the Examiner states that the electronic sphygmomanometer is mentioned but the Applicant fails to show it is incorporated into the rest of the system to perform the desired results. The Applicant submits that Claim 17 claims an electronic interface to connect with an electronic sphygmomanometer. The electronic interface is being claimed. Figure 1 clearly illustrates an optional interface to electronic sphygmomanometer 170 connected to the electronic control unit 140. Electronic sphygmomanometers are ubiquitous and extremely well known in the art of blood pressure technology as are electronic interfaces between electronic components. The Applicant submits that Claim 17 is enabled by the illustration in Figure 1 and by the Specification, sentence ten of the first paragraph under DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT.

Regarding Claim 42, the Examiner states that the Applicant has disclosed the structure and use of the invention but points to an alleged lack of specific structure regarding specific elastomeric material to be used. The Applicant respectfully disagrees with the position of the Examiner. The Examiner alluded to arguments made by the Applicant in a previous Office Action response. The Applicant submits that said arguments were directed to a small diameter tube (small in comparison to the hollow bulb 220) mostly submerged in a simulated human arm whereby a person could only press his or her fingers against the tube wall portion near the surface of the substrate to feel a simulated pulse and thereby not be able to discern the difference between simulated diastolic and systolic pressure excursions much like human blood pressure levels cannot be determined by the method of applying fingers to human blood vessel to take a pulse rate reading. The Applicant clearly states in the next to the last entire paragraph of the Specification that the elastomeric hollow bulb is intended to be broad in scope and include all vessels having at least some non-fixed surface portion that can be used by humans to sense through touch, pressure levels within the vessel. The Applicant also clearly states that one function of the pressure vessel is to provide a significant force amplification within the vessel compared to the force exerted on the walls of the relatively small diameter conduits comprising the manifold 135 and the tubing 230. Thus, due to the significant force amplification due to the large cross sectional area ratio between the hollow bulb 220 and the tubing 230, the hollow bulb can transmit a much larger force to the human touch than the force transmitted to the human touch by a small diameter tube. Also, disclosed is an incompressible member 240, in the center of the hollow bulb 220 such that the hollow bulb can be compressed to contact the incompressible member. The Applicant submits that one of ordinary skill in the art would readily recognize the level of flexibility needed in the wall material of such a hollow bulb 220 to be able to flex under a normal human hand grip to collapse the hollow bulb such that the bulb inner wall surfaces touch the internal incompressible member 240. Also, the Applicant submits by reading the specification and examining Figure 2 that one having ordinary skill in the art would recognize the large hollow bulb 200 and accompanying bleed valve 250 as being similar to a hand operated, pump bulb construction of a manual sphygmomanometer. The Specification is clear that both bulbs shown in Figure 2 are of the scale to be held and compressed by a human hand and the structure of bulb 220 shown is similar to bulb 200. The Applicant respectfully submits that Claim 42 fully meets the requirements of 35USC §112.

The Applicant has traversed the Examiner's rejections to Claims 1-11, 13-23 and 25-55 under 35USC §112. The Applicant respectfully requests that the rejections based on the alleged lack of enablement be withdrawn.

Claims Rejections under 35USC §102(b):

Claims 1, 4-6, 19, 29, 34, 36, and 39 are rejected by the Examiner under 35USC §102(b) as being anticipated by Hon (US 4,360,345).

Claim 1

Claim 1 was amended. The Examiner points to columns 9 line 57 through column 12 line 12 of Hon, (however, the Applicant is of the opinion the Examiner meant columns 9 line 57 through column 10 line 12) where the Examiner states that Hon teaches an apparatus and method for its use including: an element to generate pressurized fluid; a pressure vessel containing the pressurized fluid whereby a human can sense, through touch, pressure amplitudes within the pressure vessel; a pressure control element to control pressure levels within the pressure vessel; and an electronic control unit to interface with the fluid pressure control element to maintain simulated diastolic and systolic blood pressure levels within the pressure vessel. The Applicant disagrees that Hon teaches each and every element of Claim 1 as is required to reject a claim as being anticipated. Regarding blood pressure related simulations, Hon teaches about simulating the presence of a carotid pulse and not anything about periodic simulated diastolic and/or systolic pressure levels maintained in a pressure vessel. It is clear from Figure 14 of Hon that driving the symmetrically eccentric wheel 114 rotationally past the rubber tube 116 will not simulate human diastolic and systolic blood pressure levels in the tube but rather will provide a simple pulse train wave in the tube. Hon states "If the computer activates the electric motor to be driven at 40 revolutions per minute, eccentric wheel 114 will compress the side of rubber tube 116 creating a shock wave in the hydraulic fluid in the rubber tube 116 which will result in a 'pulse' of 80 beats per minute. This pulse rate can be varied with a digitally controlled motor and will be perceived only when the device is activated by a signal from the computer." (See column 9, lines 66-68 and column 10 lines 1-6). Hon is clearly teaching of a shock wave in the tube to simulate the presence of a carotid pulse when signaled by a computer and not maintaining human diastolic and systolic blood pressure levels in the tube or any other vessel. Also, Hon clearly states in column 5, lines 60-64 that one of the four main functions of his device is carotid pulse simulation with no mention anywhere in his disclosure of simulated diastolic and/or systolic blood pressure levels. Further, the Applicant submits that Hon does not teach that pressure amplitudes within the tube 116 may be sensed through touch expressly or impliedly, but rather only the pulse rate may be obtained. The Applicant respectfully submits that the teaching of Hon fails to teach each and every element recited in Claim 1. Hon fails to teach of an electronic control unit to interface with the fluid pressure control element to maintain simulated diastolic and systolic blood pressure levels within the pressure vessel. Also, Hon fails to teach of a pressure vessel containing the pressurized fluid whereby a human can sense, through touch, pressure amplitudes within the pressure vessel. Since each and every element of Claim1 has not been taught by Hon, the Applicant respectfully submits that the Examiner's rejection based on anticipation is improper and the Applicant requests that the rejection be withdrawn and Claim 1 be allowed.

Claim 4

Claim 4 depends on Claim 1 which has been traversed by the Applicant. Since this dependent claim includes all limitations from the independent claim on which it depends, the Applicant respectfully submits that Claim 4 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 5

Claim 5 depends on Claim 1 which has been traversed by the Applicant. Since this dependent claim includes all limitations from the independent claim on which it depends, the Applicant respectfully submits that Claim 5 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 6

The Examiner states that an electromechanical actuated pressure regulator is shown in column 9, lines 58-59 of Hon. The Applicant is unable to locate the teaching of such an element at that cited location of Hon. Moreover, the element taught in Claim 6 is a pressure sensor not a pressure regulator which are entirely different elements. The Applicant believes the Examiner meant to refer to Claim 7 where a pressure regulator is claimed. The Applicant submits that Hon does not teach of a pressure sensor to measure pressure level in the disclosed rubber tube 116. Therefore, all elements of Claim 6 are not taught by Hon. Also, Claim 6 depends on Claim 1 which has been traversed by the Applicant. For the above reasons and since this dependent claim includes all limitations from the independent claim on which it depends, the Applicant respectfully submits that Claim 6 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 19

Claim 19 was amended to include periodic pressure amplitudes and the periodic pressure amplitudes comprising at least one normal human blood pressure amplitude and at least one abnormal human blood pressure amplitude in the pressure vessel. The Examiner points to Hon column 5, line 59 for suggesting the use of a visual indicator to display indicia, which specify the pressure amplitudes within the pressure vessel. The Applicant strongly disagrees that this cited passage suggests or teaches anything about a visual display indication of blood pressure in a vessel or chamber that can be touched. There is actually no reference to any visual display of blood pressure. The Applicant also submits that Hon does not teach of at least one normal human blood pressure amplitude and at least one abnormal human blood pressure amplitude in the pressure vessel. Nor does Hon teach of a pressure vessel containing the pressurized fluid having at least one moveable surface whereby a human can sense, through touch, periodic pressure amplitudes within the pressure vessel. Therefore, Hon does not teach each and every element of Claim 19 and a rejection based on anticipation is improper. The Applicant submits that Claim 19 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 29

Claim 29 was amended to include periodic pressure amplitudes and the periodic pressure magnitudes comprising at least one of a human diastolic and human systolic pressure level. The Applicant submits that Hon does not teach of the use of any diastolic and/or systolic blood pressure simulation, with or without periodicity, in a pressure vessel containing the pressurized fluid having at least one moveable surface whereby a human can sense, through touch, pressure magnitudes of the pressurized fluid acting upon the moveable surface. Therefore, Hon does not teach each and every element of Claim 29. The Applicant submits that Claim 29 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 34

The Examiner points to Hon column 5, line 59 for suggesting the use of a visual indicator to display indicia, which specify the pressure amplitudes within the pressure vessel. The Applicant strongly disagrees that this cited passage suggests or teaches anything about a visual display indication of blood pressure in a vessel or chamber that can be touched. There is actually no reference to any visual display of blood pressure. Further, Claim 34 is dependent on independent Claim 29 with has been amended and traversed herein. Therefore, since Claim 34 has all the limitations of independent Claim 29 which has been traversed, the Applicant submits that Claim 34 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 36

Claim 36 was amended to include periodic pressure levels whereby at least one periodic pressure level comprises at least one normal human blood pressure level. The Applicant submits that Hon does not teach of the use at least one normal human blood pressure level in a pressure vessel and containing the pressurized fluid in the pressurized vessel whereby a human subject can sense the magnitude of the pressurized fluid therein by touching of the pressurized vessel. Nor does Hon teach of periodic pressure levels indicative of a simulated human blood pressure cycle. Therefore, Hon does not teach each and every element of Claim 36. The Applicant submits that Claim 36 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Claim 39

Claim 39 was amended to include periodic, simulated diastolic and systolic blood pressure amplitudes. The Applicant submits that Hon does not teach of the use of an electronic control unit to interface with the fluid pressure control element to maintain simulated diastolic and systolic blood pressure levels within the chamber. Hon does not disclose the use of either diastolic or systolic blood pressure levels in a chamber containing the pressurized fluid having a distendable surface through which a human can sense, through touch, fluid pressure amplitudes within the chamber. Since each and every element of Claim 39 has not been taught by Hon, the Applicant submits that the Examiner's rejection based on anticipation is improper and the Applicant requests that the rejection be withdrawn and Claim 39 be allowed.

Summary

The Applicant has addressed each of the Examiner's rejections of the claims based on 35USC §102(b) or 35USC §112 first paragraph either by amending claims, by traversing the rejections, or referring to a declaration. The Applicant has presented arguments why the Specification as amended, without the addition of new matter, is fully enabling to one having ordinary skill in the relevant art. The Applicant has also presented arguments why the reference (Hon) cited by the Examiner clearly does not teach all of the elements of the independent or dependent claims. Hon does not teach the production of human diastolic and/or systolic pressure levels within a pressure vessel, with or without periodicity, whereby a person can determine the pressure levels within the pressure vessel through touch. Nor does Hon teach of the production of normal and abnormal human blood pressure levels within a pressure vessel, with or without periodicity, whereby a person can determine the pressure level within the pressure vessel through touch. The Applicant believes that all of the independent claims are now in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

Also, since the dependent claims have included in them all limitations of the respective independent claims on which they depend, and based on the factual arguments made by the Applicant regarding the cited reference by the Examiner, the Applicant very respectfully submits that all of the remaining dependent claims are in condition for allowance and requests that the rejection for these claims be withdrawn.

Dependent Claim 5 was canceled, dependent claim 56 and independent claim 57 were added.

If the Examiner believes that a telephone interview would be helpful in advancing the prosecution of this application, the Examiner is requested to contact the Applicant as indicated below.

Respectfully Submitted,

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